510(k) Summary

K110839

Date:

MAR 2 5 2011

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Manufacturer:

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Contact person: Mr. Matti Tulikoura, Tel +358 400 609 507

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Contact Person: Mr. Frank Kashinski, Tel +1 414 747 6315

Trade Name:
Scanora 3D

Common Name:
Cone beam 3D X-ray system

Classification Name:
Extraoral source X-ray system (21 CFR 872.1800, product code MUH)
Computed tomography x-ray system (21 CFR 892.1750, product code JAK)

Description:
Scanora 3D is a Cone beam 3D x-ray system for Dentomaxillofacial and Head & Neck (ENT) imaging. Dedicated panoramic imaging is an option. In CT mode it generates a conical x-ray beam during rotation around a patient's head and produces two dimensional projection images on a flat panel detector. Three dimensional images are then reconstructed and viewed with 3rd party software. In panoramic mode panoramic and TMJ images can be taken in the classical way on a separate CCD detector.

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Intended Use:
The unit must only be used and operated by qualified healthcare professionals.

The unit must only be used to take 3D and (OPTIONAL) panoramic images of the dentomaxillofacial complex and the head and neck areas, including the ear, nose and throat (ENT) areas of the human skull. It must not be used to take images of any other part of the human body.

Summary of Technological Characteristics:
Scanora 3D is substantially equivalent in design, composition and function to the current Scanora 3D unit as well as to another unit currently marketed by J. Morita USA, Inc.

	Concept	SCANORA 3D	SCANORA 3D (K073350, MUH/JAK)	Morita 3D Accu-I-tomo 170 XYZ Slice view Tomograph (K073695, JAK)
1.	x-ray source	3D mode: 90 kV, 4-12.5 mA, pulsed. Pan mode: 60-81 kV, 4-8 mA continuous. kV accuracy +/5kV, Same x-ray source for 3D and Pan modes.	3D mode: 85 kV, 8-15 mA, pulsed. Pan mode: 60-81 kV, 4-8 mA continuous. kV accuracy +/5kV, Same x-ray source for 3D and Pan modes.	60-90 kV, 1-10 mA continuous
2.	Focal spot	0.5 mm	0.5 mm	0.5 mm
3.	Image detector(s)	CMOS Flat Panel + CCD for panoramic imaging	CMOS Flat Panel + CCD for panoramic imaging	Amorphous Silicon Flat Panel
4.	3D imaging technique	Reconstruction from 2D images	Reconstruction from 2D images	Reconstruction from 2D images
5.	3D's Field Of View	H60 x Ø60 mm H75 x Ø100 mm H75 x Ø145 mm H130xØ145 mm – stitched	H60 x Ø60 mm H75 x Ø100 mm H75 x Ø145 mm	H40 x Ø40 mm H60 x Ø60 mm H80 x Ø80 mm H100 x Ø100 mm H120 x Ø170 mm
6.	3D's total viewing angle	360 degrees	360 degrees	180/360 degrees
7.	Pixel size	CMOS Flat panel: 200 µm CCD for panoramic imaging: 48 µm	CMOS Flat panel: 200 µm CCD for panoramic imaging: 48 µm	127 µm
8.	Voxel size	133/200/250/ 300/350 µm	133/200/250/ 300/350 µm	80/125/160/250 µm
9.	3D scan time	10 - 26 sec	10 - 20 sec	5.4 - 30.8 sec
10.	3D's effective exposure time	2.25 - 6 sec	2.25 – 4.5 sec	5.4 - 30.8 sec

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11.	Indications for use	Scanora 3D is a Cone Beam 3D x-ray system for imaging the head and neck areas, including the ENT and dentomaxillofacial areas, for use in diagnostic support. Dedicated panoramic imaging is an option. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by qualified healthcare professionals.	Scanora 3D is a dental cone beam computed tomography x-ray system intended to image teeth, jaw and TMJ areas of the skull. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by dentists and other qualified professionals.	The Model MCT-1EX-1F8/F17 is an x-ray imaging device that acquires a 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial areas, for use in diagnostic support. The device accomplishes this task by reconstructing a three dimensional matrix of the examined volume and producing two dimensional views of this volume, displaying both two and three dimensional images. The device is operated and used by physicians, dentists and x-ray technologists.
12.	System footprint	H197cm x D140cm x W160cm	H197cm x D140cm x W160cm	H208cm x D120cm x W162cm
13,	Weight	310 kg	310 kg	Approx. 400 kg

Non-clinical Test Data:
Bench test image quality comparison between the Scanora 3D and the predicate devices was performed.

The Scanora 3D software has been successfully validated to confirm the performance of this device.

Clinical Test Data:
Clinical testing has not been conducted on this device.

Conclusion:
Based upon the similar technological/performance characteristics and image comparison as compared to the predicate devices and successful validation of the Scanora 3D software, the clinical performance of the Scanora 3D is deemed to be substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 30 2011

Mr. Matti Tulikoura
Regulatory Manager
SOREDEX, PaloDEx Group Oy
P.O. Box 148 (Street address: Nahkelantie 160)
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FINLAND

Re: K110839
Trade/Device Name: Scannora 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: June 23, 2011
Received: June 27, 2011

Dear Mr. Tulikoura:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Scanora 3D

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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